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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/823,456

04/12/2004

Patrice Nazzaro

S63.2B-14416-US01

4710

490 7590 01/06/2010
VIDAS, ARRETT & STEINKRAUS, P.A.
SUITE 400, 6640 SHADY OAK ROAD
EDEN PRAIRIE, MN 55344

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

01/06/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/823,456	Applicant(s) NAZZARO, PATRICE	
	Examiner Brian E. Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-6,9-12,15,16,18-21,24-26,30-35,38-41,47-55,59-64,79,82,85,88 and 91 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,9-12,15,16,18-21,24-26,30-35,38-41,47-55,59-64,79,82,85,88 and 91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 10/26/09 have been fully considered but they are not persuasive. Applicant argues that Nunez '514 states a maximum of three warp yarns for two filling picks and argues the amendment of more than three warp yarns is not obvious over Nunez's disclosure. However, it must be noted that when the claimed range and the prior art range are very similarly (i.e., more than 3 and up to 3) the range of the prior art establishes *prima facie* obviousness because one of ordinary skill in the art would have expected the similar ranges to have the same properties. *See in re Peterson*, 65 USPQ2d 1379, 1382, citing *titanium Metals Corp. V. Banner*, 227 USPQ 773, 779. Furthermore, the disclosure by the reference of a preferred embodiment does not teach away from the entire disclosure of the patent, all of which must be considered in the analysis of obviousness. *See In re Burckel*, 201 USPQ 67, 70. Therefore, one of ordinary skill in the art is highly skilled in the textile manufacturing such that optimizing warp yarns only involves routine skill in the process of weaving.

Applicants additionally argue that the claimed crimp sections is not obvious in view of the prior art teachings. However, the Examiner would like to know where this is illustrated in the drawings? Drawings are required to show every feature of the invention specified in the claims. If this feature is so critical, then it should be shown to distinguish a difference between what the prior art teaches regarding crimping. It is the Examiner's position that incorporation of crimping in areas of a vascular device only involves routine skill in the art and is known and taught by the references.

Applicants also allege that the teaching of Koch does not suggest different patterns along the body of the vascular structure, but admits that they are two different patterns, just located internally and externally. The Examiner would like to point out that the claims only recite different patterns along the length but do exclude the possibility of having different weaves applied as layers taught by Koch. The use of comprising language does not exclude the fact that different weaves can be applied as layers. Therefore the suggested combination, establishes the sections having the different patterns as claimed but include both, not excluded by the claims. It would be more clear if the language conveyed that the weave patterns somehow were in the same plane or to that extent.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-6,9-12,15,16,18-21,24-26,31-35,38-41,47-55,59-64,79,82,85,88,91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nunez et al. (5800514) in view of Yachia et al. (2004/93065) and in view of Liebig et al. (4517687) and Koch (4892539). Nunez et al. show (Figs. 3, 8) an implantable graft having a flat-woven tubular portion (130) and a bulbous woven section (120) contiguous with the first section. Nunez et al. disclose that the varying diameter implantable graft has a continuous warp yarns to form a seamless body, col. 3, lines 45-47,50,51, 54-58. . Nunez et al. also disclose that the woven graft has the engagingly interlaced yarns between the bulbous end and tubular section are provided with a **seamless** transition, col. 9, lines

Art Unit: 3738

58-61. In order to transition from one diameter to another, Nunez discloses the bulbous section includes an increase of at least three warp yarns for every two fill yarns, col. 10, lines 46-52,64,65. However, Nunez does not explicitly disclose more than three warp yarns used. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use more than three warp yarns for every two fill yarns, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Since the ranges abut, it is clearly obvious to one of ordinary skill to optimize about the upper and lower limits of a range. Nunez also discloses that a graft can have three sections with the second section being contiguous with the first section and including a different diameter and the third section being different than the second, col. 4, lines 29-45. It can be interpreted that more longer warp yarns are used to form the bulbous portion or larger diameter, since a tubular portion has the same number of warp yarns maintained to keep a constant diameter, (col. 9, lines 12,13,16,17) and thus there is spaced apart locations where the engaging and disengaging of the threads of warp yarns with fill yarns begin and end with the bulbous area. Nunez et al. does disclose the yarn can be monofilament or multifilament, col. 10, lines 15,16.

However, Nunez et al. do not explicitly state the middle section is bulbous or that a third section has a diameter the same as the first section and the bulbous section being radially crimped with the tubular ends free of crimps and the bulbous section comprising a different weave pattern than the tubular sections. Liebig et al. teach (Fig. 3) bulbous sections that are radially crimped, col. 3, lines 1,2. Liebig et al. additionally teach that the crimping will prevent the danger of kinking or collapse of the tubing, col. 2, lines 65-67. Liebig et al. also teach that the

Art Unit: 3738

tubular section that is not bulbous can be free from crimps, col. 3, lines 2,3. Koch teaches that different patterns can be used in the graft such that the outer section is one pattern and the inner section is another different pattern, col. 1, lines 52-59. Yachia et al teach (Fig. 6) a graft or stent-graft that has a bulbous section (610) for use in a peristaltic organ, paragraph 38. The two ends of same diameter flanking the central section stabilize the central section, this is known and common sense. It would have been obvious to one of ordinary skill in the art to utilize the teaching of Yachia and include the third section of the same diameter as a first section that flanks a central section for the graft of Nunez et al. such that it better stabilizes the device and can be used in areas such as the esophagus. Additionally it would have been obvious to incorporate crimps in the bulbous section while keeping the tubular ends free of crimps as taught by Liebig et al. with the graft of Nunez et al. as modified with Yachia et al. such that it prevents collapse within the vessel under pressure. Further it would have been obvious to one of ordinary skill in the art to use a different weave pattern on the outside of the bulbous section than a weave pattern on the inner section of the tubular ends as taught by Koch with the graft of Nunez et al. as modified with Liebig et al. and Yachia et al. such that rapid tissue ingrowth is promoted at the outer surface and adhesions prevented on the interior per Koch, col. 2, lines 3-8. Regarding claims 2,3,50,51 Nunez discloses the number of warp yarns are equal to maintain the same diameter and thus these sections would be the same, col. 9, lines 12-18.

With respect to claims 4,5,33,34,49,52,53 Nunez discloses the diameter can be about 2mm greater for the bulbous portion than the tubular portion of which can be 10mm. Regarding claims 9,11, by utilizing the different patterns as taught by Koch, it provides different density and denier.

Regarding claims 6,35,55 Nunez et al. also disclose the weave can be a plain, basket, twill or velour type, col. 10, lines 32-35.

With respect to claims 15,16,18,19,38,39,59 Nunez et al. additionally disclose polymers, such as polyethylene can be used for the yarns, col. 10, lines 8,9,14.

Regarding claims 10,12,20,21,40,41,60,61 Nunez et al. disclose the yarns can be single ply, preferably have a denier from 40-300, thus it can be 70, and made of polyester and can be twisted yarns, col. 10, lines 17,18,27-31. Nunez does disclose multiple filaments, but Nunez does not explicitly disclose including 54 filament. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use 54 filaments, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With respect to claim 31, Figs. 15,16 of Nunez illustrate multi-lumen tubular structure. Regarding claims 82,85,88,91, Nunez et al. disclose that the number of warp yarns vary as the transition goes from a smaller diameter to a larger diameter, col. 4, lines 25-27.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nunez et al. '514 in view of Yachia et al. (2004/93065) and Liebig et al. '687 and Koch '539 as applied to claim 1 above, and further in view of De Paulis (6352554). Nunez et al. in view of Yachia, Liebig and Koch is explained supra. However, Nunez as modified by Yachia et al. and Liebig et al. and Koch fail to disclose the graft has a valve. De Paulis teaches (Fig. 5) a vascular graft having a valve in a bulbous, different pattern section of a graft. It would have been obvious to one of ordinary skill in the art to use a valve as taught by De Paulis in the graft of Nunez et al. as

Art Unit: 3738

modified by Yachia et al. and Liebig and Koch such that it can be used in the coronary ostia when repairing an aorta.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

Art Unit: 3738

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738